



International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02N-0275 - Section 303: Bioterrorism Preparedness; Administrative Detention

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is submitting these comments on implementation of Section 303 of Public Health Security and Bioterrorism Preparedness and Response Act of 2002. IDFA's comments on the administrative detention provisions are submitted on its own behalf, and on behalf of its constituent organizations, the Milk Industry Foundation, the International Ice Cream Association, and the National Cheese Institute which represent approximately 850 members who operate more than 1550 processing facilities and produce eighty-five percent of all dairy products consumed in the United States.

IDFA is especially concerned that implementation of this provision fully account for the special circumstances related to producers and processors of perishable foods. In establishing an expedited administrative detention process for perishable foods, IDFA urges the Food and Drug Administration (FDA) to consider these related issues in its development of guidance:

1. What constitutes a perishable food?
2. What does credible evidence or information mean?
3. FDA should expedite the hearing process for detained perishable foods and allow for a hearing within 24 to 48 hours of the issuance of a detention order.
4. How does a detention order compare to a Class I recall?
5. Will confidentiality apply to detention orders?
6. What constitutes a secure facility?
7. Does *may* require to be marked as detained mean *must* be marked as detained?

Issue #1 -- What does perishable foods mean?

Although IDFA is unaware of any particular definition or interpretation of the phrase *perishable food*, IDFA recommends a very simple straightforward approach: FDA should define perishable foods to mean any food that in the normal course of storage, distribution, or retailing is subjected to refrigeration, including freezing, for the purpose of preserving freshness and shelf life. Such a definition appears to be easily workable and would, of course, include all dairy products.

Issue #2 -- What does credible evidence or information mean?

The Act calls for the detention of any article of food when FDA believes there is credible evidence or information that presents a threat of serious adverse health consequences or death to humans or animals.

IDFA and dairy processors are concerned about actions taken on the basis of credible evidence. Public announcements of potential terrorist activities issued in the last year have, at times, been extremely vague, but had a common theme – they were based upon the government’s acquisition of credible evidence or information. While none of the threats materialized, the episodes are nonetheless troublesome because the Act requires actions based on credible evidence or information. Credible evidence, which has thus far been incorrect each and every time, could stop the flow of food and create an enormous burden on the food industry and FDA.

IDFA and facilities that will be subject to the new regulation need clarification of what constitutes credible evidence or information. IDFA and dairy processors realize that a precise definition needs to be flexible; but, IDFA and dairy processors would appreciate some indication as to the type of evidence or information that would be required to trigger an order of detention by FDA. IDFA's belief is that credible evidence is beyond a mere suspicion, but in all likelihood, something less than clear and convincing evidence which implies an almost certainty. IDFA and dairy processors would appreciate it if FDA would address this issue and to the degree possible put the concept of credible in its appropriate context.

Issue #3 -- FDA should expedite the hearing process for detained perishable foods and allow for a hearing within 24 to 48 hours of the issuance of a detention order.

The Act calls for FDA to act upon a notice of appeal to a detention order within 5 days and to promulgate an expedited process for perishable foods. The mandate for creating expedited procedures is expressed under the heading “Period of Detention” in Section 303 (a), but for all intents and purposes, expedited procedures that do not provide for a hearing within a short period of time are meaningless. IDFA asserts that a waiting period of 24 to 48 hours from the time of request for a hearing is the appropriate timeframe given the short life of many perishable foods. Ideally, IDFA would like such hearing to take place the next day, whenever possible.

Issue #4 -- How does a detention order compare to a Class I recall?

IDFA is uncertain as to how a Class I recall is different from an order of detention. FDA should clarify whether that's a detention order applies if the goods are under the dominion and control of

the manufacturer, physically at the manufacturer's facility, and a recall applies if the article has left the manufacture's facility.

One difference that IDFA believe exists between an administrative detention and a Class I recall is that the Act has not expanded FDA's authority to order a recall. Specifically, in the event that FDA has the aforementioned credible evidence, FDA's only option would be to order a detention and not a recall.

Issue #5 -- Will confidentiality apply to detention orders?

IDFA asserts that confidentiality is critical. The Act was passed as a measure to enhance the security of the food supply; the Act was not passed to increase the public's or community's right-to-know. As virtually any state or federal intelligence or law enforcement agency would assert, security by its very nature requires a degree of discretion and confidentiality. FDA must bear that in mind when it promulgates this and the related regulations under the Act.

Further, inasmuch as there will be less than complete certainty that an article of food presents a threat of serious adverse health consequences or death to humans or animals when an order of detention is issued, FDA should be discrete. Negative public perceptions about the safety and wholesomeness of a food product can and do have enormous economic consequences. FDA must clarify that it shall treat detention orders, appeal hearings and temporary holds at ports of entry with the utmost confidentiality. To do otherwise could create a host of legal issues, which could involve any number of complex legal theories, involving unconstitutional taking of property, slander, libel, negligence, and most importantly, undermine consumer confidence.

Finally, dialog and cooperation, which are both critical in ascertaining whether or not an article of food presents a threat, will be encouraged by allowing open non-public communications. It is therefore both in the public interest and ethical to treat these matters with confidentiality until such time as a threat is definitively established as a reality, or at least until the evidence rises to the level of being clear and convincing.

Issue # 6 -- What constitutes a secure facility?

IDFA and dairy processors are uncertain about the meaning of the phrase *secured facility*. FDA needs to clarify whether a secure facility mean a building that is separate and apart from the place where the articles are normally stored, or can a secured facility be an area within the commonly used storage area. Further, does secured mean the area must contain physical barriers, such as fencing, chains and locks?

IDFA believes that if a facility itself is secured, that is, it does not permit open access to the public, as virtually all food manufacturing, processing and distribution operations are, then there should not be any need for additional security measures. It is hard to believe that Congress's intent under the secured facility provision was to prevent further tampering with an article of food, rather, it is sensible to believe its intent was to prevent those goods from being introduced into the stream of commerce. At the point goods are ordered to be detained, the damage is allegedly done and any tampering must have already occurred. The only issue that remains is to

prevent the food from being introduced into the stream of commerce and ample incentives exist to achieve that goal.

Facilities and companies do not want their products in the market place if there is any suspicion that the products may have been tampered with. Most importantly no one in the food processing industry wants a consumer to be harmed. Further, recalls are difficult and expensive and create serious public relations problems. It is highly unlikely that a food that has been subjected to an order of detention would find it way into the stream of commerce, and if it did, the statute clearly identifies that action as a prohibited act which provides a mechanism to address the situation.

IDFA therefore suggests that FDA affirm that a secured facility does not have to be a separate building, or even a specified section or location within an existing storage facility. Further, if the processing location is itself a secured facility, additional physical barriers such as walls, fencing, doors, chains and locks are not required and a facility may use reasonable means to establish that the food in question will remain, in effect, quarantined, until such time as the quarantine is removed.

Issue #7 -- Does *may* require to be marked as detained mean *must* be marked as detained?

The Act states that a detained article *may* be required to be labeled or marked, but is ambiguous about requiring the article to be removed to a secure facility. Please note that the statute initially states that the article shall be removed, which tends to indicate no discretion, but then ends with the qualifier, *as appropriate*. IDFA and dairy processors believe clarity is necessary so that non-compliance in the future will not be an issue. If FDA believes it has discretion in the requirements for labeling or marking and removing to a secured facility, FDA should state that it must make the determination, in writing, in the order of detention. If FDA fails to provide that information, in writing, in the order of detention, it should be clear that by default there is no obligation to label, mark or remove the article to a secure facility.

IDFA appreciates the opportunity to comment on the regulatory process involving Section 303 of the Act and stands ready to answer any questions to help achieve these important objectives of this section.

Sincerely,

Clay Detlefsen
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International Dairy Foods Association